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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/903,289

07/11/2001

Peter A. Burke

3056

8411

7590

08/19/2002

JOHN LEZDEY
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EXAMINER

KRISHNAN, GANAPATHY

ART UNIT

PAPER NUMBER

1623

DATE MAILED: 08/19/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/903,289

Applicant(s)

BURKE ET AL.

Examiner

Ganapathy Krishnan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Specification

The disclosure is objected to because of the following informalities: Page number is missing on one of the pages, and two pages have the same page number at the bottom. The entire specification has to be renumbered in sequence. There are large blank sections on pages 14, 16, 18, 19, 20 and on the page without a page number. On page 17, Example 1, #8, the numerals 0.20 should be moved to the right to be in line with the other percentages given in the Example. On page 19, Example 2, and page 21, Example 5, the weight percent for water is entered as g.s. It is not clear what is meant by g.s. Either g.s. should be expanded to indicate what it is, as a footnote below the table or it should be removed and actual percentage values should be indicated in the place of g.s.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 recites a composition of Claim 1 wherein the said microbicidal agent is spermicidal. It is not clear what is meant by the phrase "the said microbicidal agent is

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spermicidal". If the said agent functions both as a microbicial and a spermicidal the claim should be restated "wherein the said microbicial agent is also a spermicidal".

Claim 9 recites the composition of Claim 1 in a gel. It is not clear what "in a gel" means. If the composition is to be in the form of a gel, it should be restated "The composition of Claim 1 in the form of a gel".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lopes (USPN 5,942,478) in combination with Larsen (USPN 5,958,461), Stoner (USPN 4,925,033), Myhling (USPN 5,527,534) and Snyder et al (USPN 5,674,513),

Claims 1-18 are drawn to a universal antiviral composition which comprises an effective amount of microbicial agent, a buffer to maintain the pH of the composition not greater than 5, an effective amount of wound healing and diffusion impedance compound, the composition containing a spermicidal, an acrylic acid polymer, lubricants, detergent, cellulosic binder, the composition in a gel, buffering agent, fillers and a package comprising a condom and the said composition.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Lopes teaches a microbicidal and sanitizing soap concentrate composition capable in use of dilution with pH adjustable topical diluent to form a microbicidal solution for use in skin and non-skin surfaces against infection. The concentrate compositions are in the form of a gel. The composition of Lopes consists of materials like anionic surfactants from about 0.1 to about 95% by weight based on total weight, dextrans, cellulose ethers cellulose polymers, acrylate polymers and sulfated polymers and an acidifying agent present in the concentrate composition in an amount fixing the use form pH thereof below 5. The concentrates can be diluted with suitable inert ingredients, fillers and binders (see abstract, col. 2, lines 1-67). Hyaluronic acid can also be used in the composition (see col. 8, lines 17-23).

However, Lopes does not teach the use of any of the microbicidal agents of the instantly claimed composition, lubricants, detergent, a spermicidal and microbicidal composition and a package comprising a condom and the composition within the package.

Larsen teaches a gelled vaginal pharmaceutical composition for the prevention and treatment of diseases and the prevention of conception (see col. 1, lines 11-17). The compositions contain antiviral agents such as dextran sulfate and other sulfated polysaccharides (see col. 7, lines 18-19) and buffering agents and nonoxynol-9 as the spermicidal agent (see col. 8 lines 19-60 and col. 10, lines 27-28).

Stoner discloses a kit that combines a condom with a microbicidal cleanser to prevent sexually transmitted diseases including AIDS (see col.3, lines 5-11). He also discloses the use of nonoxynol-9 as a spermicidal, that also acts as antimicrobial agent (see col. 1, lines 57-58).

Myhling discloses a spermicidal formulation containing nonoxynol-9, a pH adjuster, sodium carboxymethyl cellulose (see Abstract; col. 15, Table 1 and col. 16, Table 2) and boric acid as an antiseptic and detergent (see col. 22, line 8 . The composition is a topical contraceptive and also provides protection against sexually transmitted diseases (see col. 15, lines 15-18).

Snyder discloses anti-bacterial/anti-viral composition containing nonoxyno-9 (also known as N-9), which further includes hydrophilic polymeric binder, which also functions as a dispersant and a suspension agent. Suitable agents include modified cellulose derivatives which are non-toxic and polyethylene glycol added as an excipient, that also functions as a lubricant, plasticizer and binder (see col. 7, lines 49-52; col. 9, lines 3-9 and lines 25-27).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings disclosed in the prior art cited to make a universal antiviral composition as instantly claimed, since the ingredients, method of making and using are all seen to be set forth in the prior art.

One of ordinary skill in the art would be motivated to do so because the combinations of the teachings in the prior art would result in a composition, which is highly effective against a wide range of pathogens and also acts as a contraceptive. This eliminates the need for an oral contraceptive. The composition is also useful for topical

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application for protecting skin and non-skin surfaces against infection and can also be diluted with water if needed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 703-305-4837. The examiner can normally be reached on 8.30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 703-308-4532. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

GK
August 14, 2002


JOHANN RICHTER
SUPERVISORY PATENT EXAMINER
GROUP 1600